



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,588	08/20/2003	Connie Sanchez	05432/100M919-US3	5265
7278	7590	05/18/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			LEWIS, AMY A	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 05/18/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/644,588	Applicant(s) SANCHEZ ET AL.	
	Examiner Amy A. Lewis	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,23,25,27,29,31,33,35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,23,25,27,29,31,33,35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>A-6</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Case

The Amendment and Remarks, filed 27 January 2006, have been entered into the application. Accordingly, claims 21 and 23 have been amended and claims 1-20, 22, 24, 26, 28, 30, 32, 34, and 36 have been cancelled.

Claims 21, 23, 25, 27, 29, 31, 33, 35, and 37, as filed 27 January 2006, are presented for examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on Application PCT/DK02/00281, filed 1 May 2002, and PA 2001 00684 filed in Denmark on 1 May 2001; the certified copy was filed in the instant application on 12 September 2005.

Response to Applicants' Arguments/Remarks:

Applicants' arguments, filed 27 January 2006, have been fully considered but they are not deemed persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Double Patenting:

The rejection of claims 21, 23, 25, 27, 29, 31, 33, 35, and 37 under the judicially created doctrine of obviousness-type double patenting over claims 40-46 of copending Application No.

Art Unit: 1614

10/468,685 (Pub. No. US 2004/0198809 A1) has been withdrawn in view of the terminal disclaimer, filed 27 January 2006 and approved 16 February 2006.

The rejection of claims 21, 23, 25, 27, 29, 31, 33, 35, and 37 under the judicially created doctrine of obviousness-type double patenting over claims 20-40 of copending Application No. 10/644,579 (Pub. No. US 2004/0192765 A1) has been withdrawn in view of the terminal disclaimer, filed 27 January 2006 and approved 16 February 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claims 23, 29, and 35 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that claim 23 has been amended to recite “to obtain a significant improvement...as measured by the CGI improvement and severity subscale.” However, this limitation still renders the claims indefinite because the term is not defined by the claim or the specification what change or how much of a change is considered to be “a significant improvement” in the patient.

Art Unit: 1614

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1614

2) Claims 21, 23, 25, 27, 29, 31, 33, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patris M, et al. ("Citalopram versus fluoxetine; a double-blind, controlled, multicentre, phase III trial in patients with unipolar major depression treated in general practice," 1996 *International Clin Psychopharm* 11: 129-136), in view of Boegesoe et al. (US Pat. 4,943,590), and further in view of Bilski et al. (US Pat. 4,764,361).

Patris et al. teach the administration of citalopram in the treatment of patients with major depression (abstract). Patients had a score of 30 on the MADRS at the beginning of the 8-week treatment period (see Fig. 1 p. 132). The reference teaches assessment of the efficacy of treatment by measuring the MADRS score as well as by the CGI severity and improvement scale (see pp. 130 and 134).

Patris et al. do not teach escitalopram (the S-enantiomer) specifically.

Boegesoe et al. teach that antidepressant drug citalopram has two enantiomers, (+)-citalopram (which is escitalopram) and (-)-citalopram, and that the entire 5-HT uptake inhibition activity resides in the (+) enantiomer (i.e. escitalopram) (see: abstract; col. 1, lines 1-28; col. 2, lines 9+). The reference also teaches separation of the two enantiomers to yield pure citalopram enantiomers (see col. 2, lines 51 – col. 7, line 25). The reference teaches "a method for alleviating depression in a living animal body subject thereto" by administering an effective amount of the compound or pharmaceutically acceptable salts (which is escitalopram), at dosages ranging from 0.10-100 mg and preferably 5-50 mg daily (overlapping the dosage of current claim 25). (See: abstract; col. 8 Table 1; col. 8, lines 55-66; claims 1-2 & 7-12).

Art Unit: 1614

While Boegesoe et al. teach pharmaceutically acceptable salts, the reference does not teach oxalate salts specifically.

Bilski et al. teaches the oxalate and crystalline oxalate salts of the (S) isoform of a racemic mixture. The reference does not teach escitalopram.

It would have been obvious to one of ordinary skill in the art to use the oxalate or crystalline oxalates salt of escitalopram in the instantly claimed method of treating severe depression, having been taught by the prior art that it is known to make oxalate and crystalline oxalate salts of a racemic compound to obtain the (S) isoform and motivated by the desired to obtain the (S)/(+) isoform salt of citalopram (i.e. escitalopram), which is known to be the racemate wherein the pharmaceutical antidepressant activity resides.

Conclusion

Claims 21, 23, 25, 27, 29, 31, 33, 35, and 37 are rejected. No claims are allowed. This rejection is made NON-FINAL due to the new/modified grounds of rejection.

Contact Information:

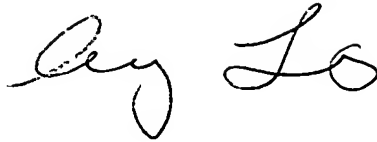
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

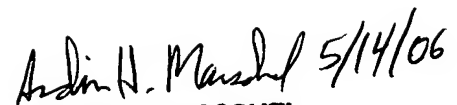
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1614

Amy A. Lewis
Patent Examiner
Art Unit 1614

Handwritten signature of Amy A. Lewis in cursive script.

Ardin Marschel
SPE
Art Unit 1614


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER